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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/334,858	06/16/1999	ALFRED E. MANN	PD-0294	5808

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EXAMINER	
LAM, ANN Y	#15

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/334,858	MANN ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13, 20-34, 51, 56, 57, 65-69 and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by Gargano et al., 5,814,015

Gargano et al. discloses a housing (616A) adapted for use on an exterior of the body; a receiver coupled to the housing for receiving remotely generated commands, see column 20, lines 23-36; a processor coupled to the housing and the receiver to receive remotely generated commands and to control the external infusion device in accordance with the commands, see column 20, lines 30-31; and an indication device (24) providing at least one of a visual indication, an audible indication or a tactile indication, to indicate when a command has been received and indicate when the

command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed from view on an individual when being remotely commanded, see column 4, line 20, and column 5, lines 49-56. The display (24) is considered an indication device providing at least a visual indication to indicate when a command has been received and indicate when the command is being utilized to control the infusion device. Alternatively, control unit (12) has a keypad for entering commands, see column 4, lines 20, and column 11, lines 40-47, and column 15, lines 53-56, and column 17, lines 23-26, and thus is considered to be an indication device providing at least a tactile indication to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device.

As to claims 2, Gargano et al. discloses a memory (64) for storing programs. The receiver is also capable of receiving software updates and facilitating remote programming of external infusion device capabilities.

As to claim 3, the external infusion device includes a memory (64) that is capable of storing a patient infusion history and pump activity, see column 13, lines 58-63.

As to claims 4, 28 and 56, the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device, see column 19, line 51 – column 20, line 8.

As to claims 5, 29, 57, and 65, the remotely generated commands are capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device, see column 19, line 51 – column 20, line 8. The audio alarm is considered to be a vibration alarm.

As to claims 6 and 30, the remotely generated commands are capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device, see column 11, lines 53-59, and column 13, lines 57-63, and column 15, lines 53-58, and column 16, lines 57-67.

As to claims 7 and 31, the remotely generated commands are capable of programming and suspending delivery of the liquid by the external infusion device, see column 17, lines 23-29, and column 11, lines 53-59, and column 13, lines 57-63, and column 16, lines 57-67.

As to claims 8 and 32, the remotely generated commands are capable of programming and activating an extended bolus delivery of the liquid by the external infusion device, see column 11, lines 53-59, and column 13, lines 57-63, and column 16, lines 57-67.

As to claims 9 and 34, the remotely generated commands are capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device, see column 11, lines 53-59, and column 13, lines 57-63, and column 16, lines 57-67.

As to claims 10 and 33, the remotely generated commands are capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device see column 11, lines 53-59, and column 13, lines 57-63, and column 16, lines 57-67.

As to claim 11, Gargano et al. discloses a remote commander including a commander housing, a keypad coupled to the commander housing for inputting

commands, and a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device, see column 20, lines 23-36.

As to claim 12, Matsumura discloses a transmitter that is capable of verifying receipt of commands from the remote commander, wherein the remote commander further includes a remote receiver to receive the verification from the device transmitter of the external infusion device, and wherein the remote commander further includes a remote indication device to indicate receipt of the verification from the external infusion device, see column 20, lines 23-36.

As to claim 13, the remote commander is considered to be sized to fit on a key ring.

As to claim 20, the remote commander is capable of providing remote commands at a distance greater than 1 inch.

As to claim 21, the processor of the external infusion device has a unique identification code, and the remote commander includes the capability to read and learn the unique identification code of the external infusion device, and the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other external infusion devices.

As to claim 22, the remote commander is considered to have a unique identification code, and the processor of the external infusion device inherently includes the capability to read and learn the unique identification code of the remote commander, and the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other remote commanders.

As to claim 23, the remote commander includes a mode that permits physician controlled programming of specific capabilities of the external infusion device to the exclusion of the user, see column 15, lines 58-60.

As to claim 24, the remote commander may also includes a link to a computer to allow computer programming to initiate or alter available capabilities of the external infusion device, see column 20, lines 23-29.

As to claim 25, the external infusion device includes a memory (64) for storing programs, and the receiver is capable of receiving software updates to facilitate remote programming of external infusion device capabilities.

As to claim 26, the remote commander is capable of receiving data from another medical device and relaying the received data tot he external infusion device, see column 20, lines 23-29.

As to claim 27, the remote commander is capable of remotely commanding and controlling the other medical device, see column 20, lines 23-29.

As to claim 51, Gargano et al. discloses an indication device, providing at least one of a visual indication, an audible indication or a tactile indication, to indicate the estimate of remaining battery power, see column 20, lines 1-2.

As to claims 65 and 66, a vibration alarm provides one or more tactile sensations to the user in response to a low reservoir alert, see column 20, lines 1-15. The audio alarm is considered to be a vibration alarm providing a tactile sensation, as claimed by Applicant.

As to claim 67, the vibration alarm provides one or more tactile sensations to the user in response to a communication from a remote commander, see column 20, lines 1-15.

As to claim 68, the vibration alarm provides one or more tactile sensations to the user in response to one or more commands to change one or more operations of the external infusion device, see column 20, lines 1-15.

As to claim 69, the vibration alarm provides one or more tactile sensations to the user during a period that the infusion device is in a suspend mode, see column 20, lines 1-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 35-43, 52-55, 58-64 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gargano et al., 5,814,015, in view of DeCant, Jr. et al., 4,443,218.

Gargano et al. discloses the invention substantially as claimed, see above. However, Gargano et al. does not disclose a bolus estimator to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body.

However, DeCant discloses a bolus estimator used in conjunction with a processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63. Also, it is inherent that there is an indication device to indicate when an amount of fluid to be infused has been calculated, since the DeCant device allows the patient to change the bolus rate to match his caloric intake during a meal.

As to claim 36, the bolus estimator includes the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 37, the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claims 38 and 39, the liquid to be infused is insulin, and the material to be ingested is carbohydrates, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 40, the bolus estimator includes a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator, see column 9, lines 11-17. The program allowing only the physician's programmer is considered to be the lockout to prevent the calculation of a bolus.

As to claim 41, the supplied values are codes representing a carbohydrate value of specific foods, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 42, the supplied values are codes representing a carbohydrate value of specific foods, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63.

As to claim 43, it is inherent that there is a duration factor to determine a valued of how long a previously infused amount of liquid will remain active in the body, wherein the determined value is used to adjust the amount of fluid to be infused, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claims 52 and 53, it is inherent that the keypad is capable of selecting one of at least two personal delivery patterns, and that there is an indication device that is capable of indicating the selected personal delivery a pattern, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

.As to claim 54, there is an indication device to indicate the basal rate profiles, see column 2, lines 20-23, and column 8, lines 47-48.

As to claim 55, there is in indication device that is capable of indicating the selected bolus type, see column 2, lines 20-23, and column 8, lines 47-48.

As to claim 58, the remote commander is considered to be portable.

As to claim 59, the transmitter wirelessly transmits commands to the receiver.

As to claims 60 and 61, remote commander is considered to have a unique identification code, and the processor is capable of storing the unique identification code.

As to claim 62, the remote commander establish non-line of sight communication with the external infusion device see column 8, 53-63, column 13, lines 3-11.

As to claim 63, the receiver is considered to include a standby mode, wherein the receiver does not receive, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claim 64, the receiver is considered to periodically become active, see column 2, lines 21-42, column 5, lines 56-59, column 8, lines 47-48 and lines 53-63, column 9, lines 11-13.

As to claims 70-72, at least two personal delivery patterns are programmable by a user, see column 2, lines 21-42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a bolus estimator as taught by DeCant Jr. et al., in the Gargano et al. device, to infuse medication at a delivery depending upon the patient's requirements. Moreover, Gargano et al. teaches a microprocessor (64), and that the drug delivery is programmable at a specific rate or amount, see column 2, lines 23-27, and column 11, lines 50-59. Furthermore, Gargano et al. teaches that the disclosed pum can be controlled by a computer or other external device, see column 20, lines 23-25. Thus, it would have been obvious to combine the teachings of DeCant Jr. et al. and

Gargano et al. to provide an infusion device as taught by Gargano et al. with a bolus estimator as taught by DeCant Jr. et al to control the delivery of medication.

Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gargano et al., 5,814,015, in view of Bentsen et al, 6,009,339.

Gargano et al. discloses the invention substantially as claimed, see above. However, Gargano et al. does not disclose the remote commander as using radio frequency or optical frequency to transmit remote commands to the external infusion device.

Bentsen discloses a telemetric communication device providing radio frequency or optical frequency signals, see column 30, lines 63-65. It would have been obvious to use radio frequency or optical frequency signals as taught by Bentsen, as the telemetry signal in the Gargano et al. device.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gargano et al., 5,814,015, in view of Dempsey et al., 5,687,734.

Gargano et al. discloses the invention substantially as claimed, see above. However, Gargano et al. does not disclose the remote commander as using infrared frequency to transmit remote commands to the external infusion device.

Dempsey discloses infrared frequency as a telemetry signal, see column 6, lines 50-60. . It would have been obvious to use an infrared frequency, as taught by Dempsey, as the telemetry signal in the Gargano et al. device.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gargano et al., 5,814,015, in view of Feierbach, 5,861,018.

Gargano et al. discloses the invention substantially as claimed, see above. However, Gargano et al. does not disclose the remote commander as using ultrasonic frequencies or audio frequencies to transmit remote commands tot he external infusion device.

Feierbach discloses use of ultrasound frequency signal as part of a transdermal communication system, see column 5, line 18. It would have been obvious to use ultrasound frequencies in the Gargano device to provide communication between the remote commander and the external infusion device. The ultrasound frequency is also considered to be an audio frequency, as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gargano et al. 5,814,015, in view of Batina et al., 4, 550,731.

Gargano discloses the invention substantially as claimed, see above. However, Gargano does not disclose the remote commander as using magnetic effects to transmit remote commands to the external infusion device.

Batina discloses magnetic frequencies as a telemetric communication device, see column 3, lines 5-11. It would have been obvious to use magnetic frequencies, as taught by Batina, as the telemetry signal in the Gargano device.

Claims 44-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gargano et al. 5,814,015, in view of Dent, 5,609,060.

Gargano et al. discloses the invention substantially as claimed, see above. However, Gargaono et al. does not disclose a vibration alarm capable of assisting in removing gas bubbles from the fluid in the reservoir during priming of the external infusion device.

Dent discloses a priming operation wherein vibration is applied to the blood channel as the pump is driven at a constant speed, thereby removing bubble from the inner wall of the channel, see column 2, lines 8-14. It is inherent that there is a vibration device.

It would have been obvious to provide a vibration device to remove bubble, as taught by Dent, on the Gargano pump, as would be desirable before using the medical pump on a patient.

Response to Arguments

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection. Gargano discloses an external infusion deivce.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

Brian L. Casler
Primary Examiner

A.L.
February 6, 2002